

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of : ANCLIFF, Rachael Ann *et al.*
Patent No. : 7,622,464
Issue Date : November 24, 2009
Title : *Morpholinyl-Urea Derivatives for Use of the Treatment of
Inflammatory Diseases*

Group / Art Unit : 1626
Examiner : ANDERSON, Rebecca L.

Confirmation No. : 5044

Docket No. : PG4784USw

MAIL STOP PATENT EXT.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**REQUEST FOR RECONSIDERATION OF
PATENT TERM ADJUSTMENT UNDER §1.705(d)**

Sir:

Applicants respectfully submit that this Request for Reconsideration of Patent Term Adjustment under §1.705(d) is timely filed, within two months of the date the patent issued.

Applicants respectfully submit that the 444 days of Patent Term Adjustment (PTA) as indicated on the Issue Notification mailed on November 4, 2009 for the above-captioned patent is incorrect and that U.S. Patent No. 7,622,464 should receive 1,108 days of PTA.

Accompanying this request is the required processing fee set forth in 37 CFR §1.18(e). The statement of facts supporting this request is set forth below pursuant to 37 CFR §1.705(b)(2). Note, the issues raised herein under 37 CFR §1.703(b)/§1.705(a) could not have been raised prior to payment of the issue fee because the total term eligible for extension could not have been calculated until actual issuance of the patent by the USPTO.

Statement of Relevant Facts/Dates:

There are several dates relevant to the calculation of patent term adjustment. Those dates are summarized below:

Filing Date:	September 27, 2004
371 Completion Date:	June 10, 2005
3-year Pendency ended:	September 27, 2007
Restriction Req. mailed:	April 1, 2008
Response to Restriction Req. filed:	October 1, 2008
Non-Final Rejection mailed:	December 26, 2008
Resp. to Non-Final Action filed:	May 29, 2009
Notice of Allowance mailed:	July 7, 2009
Issue Date:	November 24, 2009

Patent Term Adjustment under 35 U.S.C. §154

35 U.S.C. §154(b)(1) governs patent term guarantees – patent term adjustments available to compensate for delays in prosecution due to USPTO delay. 35 U.S.C. §154(b)(1) has two main sections. 35 U.S.C. §154(b)(1)(A) governs situations that arise under the “14-4-4-4 Rule,” where delay occurs for failure of the Office to issue a first action within 14 months from filing of the application, or within 4 months after various applicant responses. Delay under this subsection is referred to as “A delay.” 35 U.S.C. §154(b)(1)(B) governs situations under which pendency of the application exceeds 3 years from filing due to USPTO delay. Delay under this subsection is referred to as “B delay.”

Period of Adjustment Due to Patent Term Guarantees under 35 U.S.C. §154(b)(1)

Adjustment under 35 U.S.C. §154(b)(1)(A)(i) (“A” Delay):

Number of days beginning the day after the date that is fourteen months after the filing date and ending on the mailing date of an Office Action under 35 U.S.C. §132(a):

June 10, 2005 (371 Completion Date) + 14 months = August 10, 2006

August 11, 2006 → April 1, 2008 (Mailing Date of Restriction Req.) = + **599 days**

Adjustment under 35 U.S.C. §154(b)(1)(B)(i) (“B” Delay):

Number of days beginning the day after the date that is thirty-six months after the filing date and ending on the issue date of the patent:

September 27, 2004 + 36 months = September 27, 2007

September 28, 2007 → November 24, 2009 = + 788 days

Overlapping Period and Total Adjustment Due to Patent Term Guarantees:

According to §1.703(f), the term of a patent is entitled to adjustment under §1.702 and the term shall be adjusted for the sum of the periods calculated under paragraphs (a) through (e) (*i.e.*, “A” Delay + “B” Delay), to the extent that such periods are not overlapping, less the sum of the periods calculated under §1.704.

The subject of overlap has been addressed in *Wyeth v. Kappos*, where the US Court of Appeals for the Federal Circuit confirmed the earlier findings the US District Court for the District of Columbia, that the only way periods of time can “overlap” is if the A and B delays occur on the same day, and that the B delay begins when the PTO has failed to issue a patent within three years, not before.¹

Calculating overlap:

“B” Delay began September 28, 2007.

“A” Delay occurring September 28, 2007 or later:

September 28, 2007 (“B” Delay begins) → April 1, 2008 (Restr. Req. Mailed) = – 125 days

Here, there is an overlap period, determined according to the holding in *Wyeth*, because 125 days of “A delay” occurred after September 28, 2007 (three years after commencement of the national phase).

Total Adjustment Due to Patent Term Guarantees:

599 days + 788 days – 125 days = 1,262 days

Period of Limitations to Patent Term Adjustment under 35 U.S.C. §154(b)(2)

Reductions Due to Applicant Delay under 35 U.S.C. §154(b)(2)(C)(i):

¹ *Wyeth v. Kappos*, 93 USPQ2d 1257 (Fed. Cir. 2010), affirming *Wyeth v. Dudas*, 580 F. Supp. 2d 138, 142.

Number of days beginning the day after the date that is three months after the mailing date of an Office Action and ending on the date the reply was filed (37 C.F.R. §1.704(b)):

July 2, 2008 → October 1, 2008 = - 91 days

March 27, 2009 → May 29, 2009 = - 63 days

Total Reductions to Adjustment Due to Limitations: - 91 days - 63 days = - 154 days

Total Adjustment (Patent Term Guarantees - Limitations): 1,262 days - 154 days = 1,108 days

Accordingly, Applicants hereby request that the U.S. Patent Office correct the calculation of the Patent Term Adjustment for the present Application to 1,108 days.

PAYMENT OF FEES (check one box)

☐ A check in the amount of \$_____ is enclosed for the consideration of this Request as required by 37 CFR §1.18(e).

☒ The Commissioner is hereby authorized to charge the required fees (\$200.00) or credit any overpayment to Deposit Account No. 07-1392.

Respectfully submitted,

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